REMARKS

The Official Action mailed February 26, 2003, and the prior art relied upon therein have been carefully reviewed. The claims in the application remain as claims 1-11, and these claims define patentable subject matter warranting their allowance. Accordingly, applicants respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under §119 is noted.

The issues raised by the examiner under the heading "Claim Objections" with regard to claim 8, 9 and 11 have now been addressed above. These claims are now in proper form for U.S. prosecution, and applicants respectfully request examination on the merits of claims 8 and 9.

Claims 1-9 have been rejected under the second paragraph of §112, as not reciting a method. The same claims have been rejected under §101 as being in a non-statutory format. These rejections are respectfully traversed.

Applicants agree with these rejections only to the extent that claims recited in a European "use" format are not considered proper under U.S. practice. Applicants disagree that the claims as originally drafted would have been

confusing to those skilled in the art. Accordingly, applicants submit that the claims as previously drafted, particularly considered in light of applicants' specification (consistent with the law), would not have been confusing to those skilled in the art, and therefore the claims in their previous form are fully in accordance with §112. At **worst**, such claims in their previous form might be considered objectionable, but **only** as to form.

In order to improve the form consistent with U.S. practice, a number of cosmetic amendments have been made in claims 1-9. Such amendments are of a formal nature only, i.e. made to place the claims in good form consistent with U.S. practice. Such amendmetns are not "narrowing" amendments because the scope of the claims in these regards has not been reduced.

Applicants respectfully request withdrawal of the rejections under §101 and the second paragraph of §112.

Claim 10 has been rejected under §101 as being allegedly directed to non-statutory subject matter. This rejection is respectfully traversed.

Applicants respectfully note that islets of Langerhans coated with a heparin conjugate are not a thing which occurs in nature. Claim 10 in its original form is indeed a "manufacture" because it is the product resulting

from the islets of Langerhans being coated with a heparin conjugate.

Nevertheless, the examiner has helpfully suggested a new form for claim 10 which does not change the meaning or scope thereof, and applicants have adopted the examiner's helpful suggestion. Applicants request withdrawal of the rejection.

Claims 1-4, 10 and 11 have been rejected under §102 as anticipated by Wagner et al DE '440 (Wagner). This rejection is respectfully traversed.

Wagner, referred to as D1 in the International Preliminary Examination Report (IPER), describes microcapsules used in transplantation surgery. The microcapsules are made of organic material and allow slow release of substances. In the International Preliminary Examination Report, it was held that the wording "in the form of isolate islets" in claim 1 does not clearly exclude the microencapsulated islets of Wagner.

However, in fact, the present invention is quite different from Wagner. In the present invention, the islets of Langerhans are not encapsulated. Instead, they are coated, prior to transplantation, with a clotting preenting agent. As claim 1 now specifies that the isolated islets are not artificially encapsulated, it should be clear that claim 1 and

the claims which depend therefrom are not anticipated by Wagner.

Applicants respectfully request withdrawal of the rejection.

Claims 1 and 5-7 have been rejected under §102 as being anticipated by the Lenchow et al 1992 publication (Lenchow). This rejection is respectfully traversed.

Lenchow describes the use of human islets of Langerhans for transplantation into mice. The major problem discussed in Lenchow concerns the risk of rejection after transplantation, and there is no discussion of (or apparent recognition of) the problem of coagulation, as in the present invention. The coagulation process, which is normally started at the moment the islets of Langerhans are transplanted, is not initiated if a clotting preventing agent is used.

Applicants do not see that Lenchow discloses or teaches the coating of the islets of Langerhans with a clotting preventing agent. Lenchow does not anticipate applicants' claims, and the rejection should be withdrawn. Such is respectfully requested.

Claims 1-4, 10 and 11 have been rejected under §102 as anticipated by Soon-Shiong et al USP 5,705,270 (Soon-Shiong). This rejection is respectfully traversed.

Soon-Shiong discloses microcapsules for use in conjunction with biological material, e.g. a polymerizable alginate or a composite thereof with polyethylene glycol.

The present invention does not involve, and applicants do not claim, any such microcapsules as disclosed by Soon-Shiong. Applicants' invention is clearly distinct from Soon-Shiong because the present invention does not involve or comprise encapsulation of islets of Langerhans.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 5 has been rejected under §103 as obvious from Soon-Shiong. This rejection is respectfully traversed.

The rejection acknowledges that Soon-Shiong does not disclose use of a clot preventing agent to produce a drug for administration for transplantation of insulin producing cells in the form of isolated islets to patients with insulin dependent diabetes mellitus wherein the preventing agent is an inhibitor of platelet activation. However, in spite of such a lacking of any such teaching in Soon-Shiong, the PTO takes the position that it is nevertheless obvious to do, even though there is no evidence in support of this conclusion, e.g. no supporting or subsidiary citation pointing to any such obviousness. The reasoning of the rejection thus appears to be based on applicants' specification which is the only

teaching in the present record of the present invention, and which of course was not available to the person of ordinary skill in the art at the time the present invention was made.

Moreover, claim 5 is further patentable because it depends from and incorporates the subject matter of claim 1. Soon-Shiong does not make obvious the coating of isolated islets with a clotting preventing agent.

Applicants respectfully request withdrawal of the rejection.

The Office Action on page 8 refers to an Information Disclosure Statement. However, applicants filed no Information Disclosure Statement in the present application.

On the other hand, a search was conducted during the International phase, and the PTO has been provided with a copy of the International Search Report. It is believed that the International Bureau should have provided the PTO with copies of the references cited during the International search. MPEP 609 at page 600-119 (August 2001) indicates that the examiner will consider the documents cited in the International Search Report when copies of the documents are present in the national stage file.

Applicants further note for the record the provisions of 37 CFR 1.104(a)(1), and (b) as well as (c)(2). Applicants respectfully request the examiner to give full

consideration to all available potentially material prior art which may exist, including any possibly material prior art uncovered during the International Search and listed in the International Search Report which the examiner may not have yet considered.

Applicants respectfully request favorable reconsideration and allowance.

Respectfully submitted,

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